FDA 510(k) Premarket Notification

K232878 TransLoc 3D

CLEARED

Oct 17, 2023
29 days to decision

K232878 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k232878/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Sep 18, 2023
Decision date	Oct 17, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Foundation Fusion Solutions, LLC (Dba Cornerloc)**
Location	Tulsa, OK, US
Contact	Robert Compton
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Watershed Idea Foundry**
Contact	Jeffrey Brittan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov